REMARKS

In an Official Action dated November 3, 2005, the Examiner withdrew claims 2, 11-13 and 16 from consideration and rejected claims 1, 3-10 14, 15 and 17-19. Applicants request that the Examiner reconsider the rejection in light of the following discussion.

Preliminarily, Applicants note that the amendment to the first paragraph of the specification is made in order to clarify a clerical mistake in the specification. The first paragraph inadvertently identified the parent application as 09/527,612. The correct application was set forth in the transmittal papers that accompanied the application, along with the declaration that properly identified the application number. The first paragraph now reflects this application number. Further, Applicants believe that the amendments to the specification set forth above eliminate the need for the drawings changes requested by the Examiner. Accordingly, Applicants request that the Examiner reconsider the objection to the drawings.

Claims 1, 3-10, 15 and 17-19 were rejected under the judicially created doctrine of obviousness-type double patenting. Submitted with this Response is a Terminal Disclaimer. Accordingly, Applicants request that the Examiner reconsider the double patenting rejection.

Claims 1, 3-10, 14, 15 and 17-19 were rejected as anticipated by Erskine 5,690,619. However, the structure in the Erskine device is quite different from Applicants' device and does not teach or suggest the features in the pending claims.

Erskine discloses a number of embodiments of a catheter insertion device having a retractable needle. In the cited embodiment in Figs. 6-8, the device includes a latch 250 that releasably engages a needle hub 221. When the latch 250 is actuated, the latch releases the needle hub and a spring displaces the needle rearwardly. To

actuate the latch 250, the device includes an elongated wire latch actuator 260. The latch actuator is a pair of wire rails 269 that hook onto the catheter hub 11, so that pulling the catheter hub off the device pulls the rails 269. The latch actuator rails 269 overlie the latch, preventing the latch from pivoting away from the needle hub–in other words, the latch does not have room to pivot away from the needle hub as long as the latch actuator rails 269 overlie the latch. Since the latch actuator is hooked onto the catheter hub, pulling the catheter hub off the device pulls the rearward end of the latch actuator rails 269 forwardly so that the latch actuator is clear of the latch 250. The latch is then free to pivot to release the needle for retraction.

In contrast to the Erskine devices, Applicants devices are simplified devices that ensure that the needle is retracted automatically when the catheter is inserted into the patient. At the same time, Applicants' device may be configured to allow the retraction to be delayed if desired, while at the same time ensuring that the needle automatically retracts.

Turning now to the claims, claim 1 recites a retractable needle device having a needle retainer fixedly connected with the insertion needle. Referring to Figs. 25-27, Applicants' device includes a needle retainer that is fixed to the needle, such as by epoxy (see Application, page 23 lines 16-18). In contrast, the device in Erskine has a latch 250 that releasably engages the needle hub; it is not fixedly attached to the needle.

Further, claim 1 recites that the needle retainer is an elongated arm engaging the catheter. The latch 250 in Erskine does not engage the catheter. The only element that engages the catheter is latch actuator 260, but the latch actuator is not fixedly attached to the needle. If it were, the device would not operate. Further still, claim 1 recites that the needle retainer releases the needle upon disengagement of the catheter from the arm. The only arm that engages the catheter 11 is the latch actuator 260, and

it does not disengage the catheter to cause retraction. In fact it is the engagement between the latch actuator and the catheter that causes actuation of retraction. Since Erskine does not teach or suggest the features of claim 1, Applicants request that the Examiner reconsider the rejection of claim 1 and dependent claims 2-5.

The features from the dependent claims provide further distinctions between the Erskine device and the claims. For instance, claim 3 recites that the elongated arm of the needle retainer comprises a latch releasably engaging the housing. In contrast, the device in Erskine does not have such a latch. The latch 250 engages the needle hub 221, not the housing.

Further, claim 4 recites that the device includes a flashback chamber integrally formed with the needle retainer. As can be seen in the drawings, Applicants' device includes a needle retainer 740 that is integrally molded with the flashback chamber 750. In contrast, the Erskine device has a separately manufactured flashback chamber 221 that is not and cannot be integrally formed with the latch 250. These additional differences between claims 3 and 4 further distinguish the claims from Erskine.

Turning to claim 6, the claim recites a retractable needle device that is automatically retractable but which includes the ability to delay retraction if desired. As discussed in the application, Applicants' device includes a needle retainer 740 in the form of an elongated arm that engages the catheter hub. When the catheter is removed from the device the catheter hub disengages the needle retainer arm 740 allowing the arm to pivot outwardly to actuate retraction. However, in some instances, the medical professional may desire to delay retraction of the needle. In such an instance, the medical professional may simply hold down the needle retainer arm to hold the needle. For this reason, Applicants' device may include a manually actuable surface operable to retain the needle in the exposed position.

In contrast to Applicants' device, the Erskine does not have such a feature to delay retraction. The Official Action indicates that the latch actuator 260 is an exposed surface, but there is no teaching that this is an exposed surface manually operable to retain the needle retainer in the latched position. How could the latch actuator 260 be manually operated to retain the needle retainer in the latched position? The only way to prevent the latch 250 from being actuated is by not pulling the catheter 11 off the device. Since nothing in Erskine teaches or suggests the features of claim 6, Applicant request that the Examiner reconsider the rejection of claim 6-13.

Referring to claim 14, there is no teaching or suggestion in Erskine of the steps in claim 14 and the Office Action does not even attempt to show how Erskine reads on claim 14.

Claim 14 recites a method for inserting an IV catheter that includes disengaging the catheter frm a housing and selectively manually engaging the needle retainer to impede retraction of the needle and releasing selective engagement with the needle retain to disengage the needle retainer from the needle. None of the feature are taught or suggested by Erskine. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 14 as anticipated by Erskine.

Referring to claim 15, Erskine does not teach or suggest the features of claim 15. For instance, claim 15 recites a needle retainer substantially permanently attached to the needle. Erskine specifically teaches a releasable connection. In fact, the device will not operate if a permanent connection is used. Accordingly, in light of this and other differences, Applicant requests that the Examiner reconsider the rejection of claims 15-29.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if

the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **Three** month beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

May 2, 2006
Date of Certificate

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